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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/389,318	09/03/99	SUZUKI	0 001560-372
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EXAMINER

MARX, I

ART UNIT

PAPER NUMBER

1651

DATE MAILED:

08/31/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/389,318

Applicant(s)
Suzuki et al.

Examiner
Irene Marx

Group Art Unit
1651



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1, 3-8, 10-15, and 17-30 is/are pending in the application.

Of the above, claim(s) 8, 10-15, and 17-30 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1 and 3-7 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☒ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The application should be reviewed for errors.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 3-7 drawn to a process of making arachidonic acid using *Mortierella*, classified in Class 435, subclass 135, for example.

II. Claims 8 and 10-14 drawn to a process of making γ -bishomolinoleic acid using *Mortierella*, classified in Class 435, subclass 135, for example.

III. Claims 15 and 17-21 drawn to a process of making eicosapentaenoic acid using *Mortierella*, classified in Class 435, subclass 135, for example.

IV. Claims 22-25 and 27-29 drawn to a feed composition comprising *Mortierella*, classified in Class 426, subclass 60, for example

V. Claims 26 and 30 drawn to a strain of *Mortierella* and a feed composition thereof, classified in Class 435, subclass 254.1, for example.

Inventions V and I-III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using such as in a process for obtaining antibodies or as host cells in processes involving the use of recombinant DNA. Moreover, the process for using the product as claimed can be practiced with another material different product, such as genetically engineered cells or the various strains recited herein. Note also the difference in the scope of the claims.

Each of groups IV and V is directed to separate and distinct inventions, Group III is directed to a specific strain of belonging to *Mortierella*, while group V is directed to a feed composition comprising any strain of *Mortierella*. The products of groups IV and V would be expected to have distinct morphological, functional and physiological properties as evidenced by their divergent classification and process of making. The specific strain as claimed was isolated from soil by a selection process. These products are not required one for the other.

The method of Group I is directed to a process of making arachidonic acid, the method of group II is drawn to a process of making γ -bishomolinoleic acid and the method of group III is drawn to a process of making eicosapentaenoic acid. These methods are distinct both physically and functionally, require different process steps and produce different products.

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches (as indicated by the different classification). The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of Group I would not necessarily anticipate or make obvious the any of the other groups.

For these reasons restriction for examination purposes is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

During a telephone conversation with Ms. Gardner on August 17, 2000 a provisional election was made with traverse to prosecute the invention of Group I, claims 1 and 3-7. Affirmation of this election must be made by applicant in replying to this Office action. Claims 8, 10-15, and 17-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim 4 is rejected under 35 U.S.C. § 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants state at page 8, lines 30 et seq. that the species *M. alliacea* is known. However, it is not found in the ATCC Catalogue of Filamentous Fungi, 1996. It is unclear what the properties of this species are. Is this a new species? Clarification is required.

Rejections under 35 U.S.C § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a novel strain of *Mortierella* to obtain a specific product. The written description of that strain and the method of isolating is insufficiently reproducible. Therefore, a deposit for patent purposes is required. The specification discloses at page that SAM 2197 was deposited at National Institute of Biosciences and Human Technology of the Agency of Industrial Science and Technology under Budapest Treaty conditions on 3/3/97.

For compliance with the rule, it must be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent. MPEP 2403.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 5, and 6 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kyle.

Kyle teaches a method of making arachidonic acid with a strain of *Mortierella alpina* which is clearly resistant to high carbon source concentration, since it produces arachidonic acid using a concentration of glucose of 8% and wherein soy flour appears to be an additional carbon source. (See, e.g., Example 7)

Claims 1, and 3-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kyle.

As noted in the rejection under 35 U.S.C. §102, Kyle teaches a method of making arachidonic acid with a strain of *Mortierella alpina* which is clearly resistant to high carbon source concentration, since it produces arachidonic acid using a concentration of glucose of 8% and wherein soy flour appears to be an additional carbon source (See, e.g., Example 7). The reference differs from the claimed invention in that *Mortierella alliacea* or the deposited strain are not disclosed. However, inasmuch as it acknowledged that members of *Mortierella alliacea* are similar to *M. alpina*, one of ordinary skill in the art would reasonably expect similar properties with respect to arachidonic acid production as those of *M. alpina* strain taught by Kyle. With respect to a process of culturing the deposited strain SAM 2197, it is apparent that the results of Table 1, for example, pertain to a process of culturing using glucose in conjunction with yeast extract as carbon source and under specific process conditions.

Serial No. 09/389318
Art Unit 1651

-6-

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196 .



Irene Marx
Primary Examiner
Art Unit 1651